

1 ZOYA YARNYKH, SBN 258062  
2 People With Disabilities Foundation  
3 507 Polk Street, Suite 430  
4 San Francisco, CA 94102  
Phone: (415) 931-3070  
Fax: (415) 931-2828  
zyarnykh@pwdf.org

5 Attorneys for Plaintiff

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8 UNITED STATES DISTRICT COURT  
9 NORTHERN DISTRICT OF CALIFORNIA

10 STEVEN BRUCE,

11 Plaintiff,

12 vs.

13 ALEX M. AZAR II, Secretary of the  
14 Department of Health and Human Services,  
15 ENVISION INSURANCE COMPANY,  
16 BLUE SHIELD OF CALIFORNIA, and  
17 DOES 1-50,

18 Defendants.

19 Case No.

20 **COMPLAINT FOR:**

- 1. PRESCRIPTION COVERAGE UNDER TITLE XVIII OF THE SOCIAL SECURITY ACT – MEDICARE PART B AND PART D;**
- 2. INJUNCTIVE RELIEF;**
- 3. DECLARATORY RELIEF;**
- 4. MONETARY DAMAGES;**
- 5. DUE PROCESS VIOLATION;**
- 6. VIOLATION OF SECTION 504 OF THE REHABILITATION ACT OF 1973;**
- 7. VIOLATION OF THE AMERICANS WITH DISABILITIES ACT AS TO THE NON-FEDERAL DEFENDANTS**
- 8. JURY DEMAND**

23  
24 **I. PRELIMINARY STATEMENT**

- 25 1. The Plaintiff Steven Bruce is a Medicare beneficiary who is enrolled in Medicare, Part  
26 B (42 U.S.C. § 1395w-21 *et seq.*) and a Medicare prescription drug plan, Part D (42  
27 U.S.C. §§1395j-1395w-6) and who sought coverage from his plan for a medically  
28 necessary prescribed medication, Serostim. This complaint is for judicial review of a

final decision of the Department of Health and Human Services (DHHS), made by the Medicare Appeals Council (AC) on July 12, 2018, denying coverage for the medication. Plaintiff requires Serostim for treatment of his wasting disease caused by an auto-immune disease, lipodystrophy. The DHHS does not question the efficacy of Serostim in managing Plaintiff's serious life threatening medical condition. The DHHS further agrees that Mr. Bruce has been unable to take other medications to treat his condition. Nonetheless, the DHHS denied coverage based on an overly restrictive interpretation of what constitutes a "medically accepted indication" under the statute.

## II. THE PARTIES

2. Plaintiff Steven Bruce is a resident of San Francisco, California. He is, and has been, a Medicare beneficiary at all times relevant to this action.
3. Defendant, Alex M. Azar II, is the Secretary of the United States Department of Health and Human Services, and as such is responsible for the administration of the Social Security Act, Title XVIII, the Medicare program. The Secretary is a proper Defendant in this appeal of the AC decision, and is being served in his official capacity. *See* 42 C.F.R. §423.2136.
4. Defendant Envision Insurance Company, a corporation doing business in California, provides EnvisionRx Plus Silver, a Medicare-approved prescription drug plan providing prescription drug coverage under Medicare Part D.
5. Defendant Blue Shield of California (Blue Shield) is a California corporation and provides Blue Shield of California Enhanced Prescription Drug Plan, a Medicare approved drug plan providing prescription drug coverage under Medicare Part D.

## III. VENUE

6. Venue is proper in this District by reason of Plaintiff's residence in San Francisco County, California. *See* 42 C.F.R. § 423.2136(b).
7. Pursuant to Local Rule 3-2(d), this action should be assigned to either the San Francisco or Oakland Division.

#### **IV. JURISDICTION**

8. The Plaintiff brings this action pursuant to § 42 U.S.C. § 1395w-104(h)(1) which incorporates the requirements of 42 U.S.C. § 1395w-22(g)(5) and 42 U.S.C. § 405(g), to appeal a final decision of the DHHS that denied coverage for Serostim.
  9. The Plaintiff has exhausted his administrative remedies. The Administrative Law Judge (ALJ) Appeal Numbers are 1-5125326621R1 (EnvisionRx Plus Silver) and 1-6176167691R1 (Blue Shield).

## V. FACTS AND ADMINISTRATIVE PROCEEDINGS

10. Serostim is approved by the Food and Drug Administration (FDA) for HIV patients with wasting or cachexia to increase lean body mass and body weight and to improve physical endurance, and for short bowel syndrome. Non-FDA approved uses are for fat maldistribution from HIV infection.

#### **A. EnvisionRx Plus Silver**

11. Plaintiff is a duly-qualified Medicare beneficiary based on age. In 2016, his Part D drug plan was administered by EnvisionRx Plus Silver through Defendant Envision Insurance Company.
  12. Mr. Bruce was diagnosed with lipodystrophy and life-threatening wasting syndrome in on or about March of 2016. Plaintiff does not have HIV.
  13. His primary care physician Dr. Louis Cubba prescribed Serostim to halt Plaintiff's severe and dramatic weight loss. Plaintiff's weight dropped to 132 pounds in the beginning of 2016. Plaintiff is 5'11" tall. Plaintiff regained approximately 10lbs after starting Serostim regimen. It is the only drug that helped Plaintiff regain weight.
  14. Dr. Cubba requested coverage of Serostim from Plaintiff's Part Medicare plan, EnvisionRx Plus Silver on May 31, 2016. The plan denied coverage on June 3, 2016 on an alleged basis that the requested medication to treat the condition was neither an approved use by the FDA, nor supported in a drug compendia approved by Medicare.

15. The Plaintiff timely filed a reconsideration request with the Medicare Part D Independent Review Entity (IRE). The IRE issued an unfavorable decision on September 16, 2016.
16. Mr. Bruce timely requested a hearing with an ALJ on November 15, 2016. On October 21, 2016, a telephone hearing was held by ALJ James Myles.
17. On November 15, 2016, Judge Myles issued an unfavorable decision. ALJ Gulin erroneously dismissed Plaintiff's request for hearing as to Medicare and Blue Shield by assuming that this appeal was also against Envision when it was against Blue Shield, *see infra*.
18. Plaintiff timely appealed to the ALJ's decision to the AC, which remanded the case back to the ALJ for further development of the record on December 20, 2017.
19. Plaintiff provided an example of how Gabapentin (Neurontin) was prescribed off-label for pain, rather than an anti-seizure medication. Dr. Watson, a medical expert, testified at the hearing about another drug, Lyrica, which, like Gabapentin, was also used off-label purposes and covered under Medicare Part D. This further supports Plaintiff's position that there is no reason to deny him coverage, either under the FDA-approved use for cachexia/wasting because it is unknown whether HIV actually causes this condition, or for an off-label use for lipodystrophy.
20. ALJ Myles issued another unfavorable decision on March 30, 2018.
21. Plaintiff timely appealed again to the AC, which issued an unfavorable decision on July 12, 2018.

**B. Blue Shield**

22. Plaintiff refers to, and incorporates herein by reference, all preceding paragraphs as though fully set forth herein.
23. For benefit year 2017, Plaintiff's Part D plan was administered by Blue Shield (Blue Shield of California Enhanced Prescription Drug Plan).

- 1           24. The plan did not approve Serostim for Plaintiff because his “diagnosis of  
2           Lipodystrophy is not a ‘medically accepted indication’ use of Serostim.” Blue Shield  
3           argued that Serostim was an off-label use not included in the compendia for Plaintiff’s  
4           life-threatening condition.
- 5           25. Plaintiff timely requested reconsideration from IRE.
- 6           26. IRE denied coverage on April 17, 2017. IRE asserted that there were no citations in the  
7           Medicare-approved compendia supporting Serostim for Plaintiff’s condition,  
8           lipodystrophy.
- 9           27. Plaintiff timely requested a hearing before an ALJ on May 1, 2017. Following the  
10          initial request, ALJ Jeffrey S. Gulin dismissed the case because of the previous  
11          decision issued by ALJ Myles. Plaintiff timely appealed the dismissal with the AC,  
12          which remanded the case back to the ALJ for further development on December 20,  
13          2017.
- 14          28. On February 8, 2018, Plaintiff had a telephonic hearing with Judge Gulin. Plaintiff  
15          argued that cachexia is a synonym for wasting syndrome and both are medically  
16          equivalent. Plaintiff also cited National Institutes Health (NIH) studies that lead to the  
17          conclusion that it was not the HIV that led to lipodystrophy, but the anti-viral agents  
18          used to treat HIV. Plaintiff also argued that \$2,000 of the \$14,000 retail cost of  
19          Serostim was covered by Medicare Part B as further proof that Serostim was not being  
20          used for an unapproved “off-label” use under to the statute.
- 21          29. On March 15, 2018, ALJ Gulin issued an unfavorable decision.
- 22          30. Plaintiff timely appealed to the AC, which issued an unfavorable decision on July 12,  
23          2018, relating and consolidating both Administrative Law Judge (ALJ) Appeal  
24          Numbers are 1-5125326621R1 (EnvisionRx Plus Silver) and 1-6176167691R1 (Blue  
25          Shield).
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- 1       31. Plaintiff now timely appeals the final July 12, 2018 decision of the AC and is properly  
2       before this Court. The amount in controversy exceeds \$1,600 and as of the date of  
3       filing this Complaint is approximately \$70,000.00
- 4       32. There is no practical difference between HIV or the anti-viral drugs which may cause  
5       the auto-immune disease that Plaintiff has, lipodystrophy. Both are auto-immune  
6       diseases which result in a life-threatening wasting syndrome for which Serostim is  
7       prescribed. Plaintiff's use of Serostim is for a medically accepted indication within the  
8       meaning of § 1927(k)(6) of the Social Security Act, 42 U.S.C. § 1396r-8(k)(6). He is  
9       entitled to Medicare coverage for this drug.
- 10      33. Medicare Part B covered \$2000 of the cost of Serostim, reducing the price to  
11       approximately \$12,500. *See* 42 U.S.C. § 1395w-21 *et seq.* This further supports  
12       Plaintiff's position that his Serostim should be covered by Medicare Part D, and is not  
13       used off-label.

14      **VI. CAUSES OF ACTION**

15      **A. Medicare Part B (42 U.S.C. § 1395w-21 *et seq.*) and Part D (42 U.S.C. §1395j-  
16           1395w-6) Coverage – Title XVIII, Against Defendants DHHS, Envision and  
17           Blue Shield**

- 18      34. Plaintiff refers to, and incorporates herein by reference, all the preceding paragraphs as  
19       though fully set forth herein.
- 20      35. The DHHS's decision denying Plaintiff's claim for Medicare coverage of Serostim is  
21       not supported by substantial evidence and is incorrect as a matter of law, on the  
22       following grounds:
- 23       a. Substantial evidence, when the record is viewed as a whole, supports that  
24           Serostim is a covered under both Parts D and B (approximately \$2,000.00 of  
25           \$14,500 was covered under Part B apparently because it is an injectable.)

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1                   b. The DHHS's decision is based on errors of law in that the AC's decision was  
2                   made without legal basis and its interpretation of "medically accepted  
3                   indication" is unlawfully restrictive and has no rational basis.

4                   **B. Violation of the Due Process Clause of the Fifth Amendment to the United  
5                   States Constitution Against DHHS**

6                   36. Plaintiff refers to, and incorporates herein by reference, all the preceding paragraphs as  
7                   though fully set forth herein.

8                   37. The DHHS, in upholding both the of the decisions of ALJ Myles and ALJ Gulin,  
9                   violated Plaintiff's due process rights under the Fifth Amendment to the United States  
10                  Constitution.

11                  38. Neither ALJ Myles nor ALJ Gulin made a finding that it was HIV, as opposed to  
12                  antiviral medications used to treat HIV, which caused wasting disease or lipodystrophy  
13                  in HIV-positive individuals.

14                  39. Although more research is needed, some studies have shown that some antiviral  
15                  medications have been associated with lipodystrophy in HIV-positive population as  
16                  opposed to the HIV itself.

17                  40. The DHHS did not find that lipodystrophy or wasting/cachexia is caused by HIV. In  
18                  Plaintiff's case, the cause of lipodystrophy/life-threatening weight loss is likewise  
19                  unknown, linked to an unidentified virus. The DHHS/AC states in its decision that it  
20                  makes a *de novo* review, and only reviews what is in Beneficiary's Appeals Council's  
21                  brief if Beneficiary is represented. Beneficiary (Plaintiff Steven Bruce) was not  
22                  represented.

23                  **C. Violation of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794,  
24                  Against Defendant DHHS.**

25                  41. Plaintiff refers to, and incorporates herein by reference, all the preceding paragraphs as  
26                  though fully set forth herein.

- 1           42. Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 ("Section 504")  
2           provides that no otherwise qualified individual with a disability in the United States  
3           shall, solely by reason of his or her disability, be excluded from the participation in, be  
4           denied the benefits of, or be subjected to discrimination under any program or activity  
5           receiving Federal financial assistance or activity conducted by any federal agency.
- 6           43. Plaintiff is entitled to Section 504 protection as an individual with a disability - wasting  
7           disease and lipodystrophy.
- 8           44. Defendant DHHS is a federal agency and is bound by the regulations it has  
9           promulgated under Section 504 of the Rehabilitation Act, 45 C.F.R. Part 85.
- 10          45. As alleged herein, the DHHS has and continues to discriminate against Plaintiff by  
11           denying coverage for Serostim under Medicare Part D – a drug without which Plaintiff  
12           can die.
- 13          46. By providing coverage for Serostim only to individuals who have HIV, the DHHS  
14           denied Plaintiff, as an individual with a disability, the opportunity to participate in, or  
15           benefit from, DHHS's aids, benefits, or services afforded to those with HIV.
- 16          47. There is no rational basis for providing Serostim to treat cachexia, wasting syndrome  
17           or lipodystrophy only to individuals who have been diagnosed with HIV, as Plaintiff's  
18           condition is auto-immune in nature, not genetically based, and is a product of a virus.  
19           The DHHS provided no evidence to the contrary.
- 20          48. Plaintiff has exhausted his administrative remedies by alleging Section 504 violations  
21           before the ALJ and again before the AC.
- 22          **D. Violation of Title III of the Americans with Disabilities Act (ADA) Against**  
23          **Defendants Envision Insurance Company and Blue Shield of California.**
- 24          49. Plaintiff refers to, and incorporates herein by reference, all the preceding paragraphs as  
25           though fully set forth herein.
- 26          50. The ADA prohibits discrimination based on disability.
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- 28

51. Defendants Envision Insurance and Blue Shield have, and continue to, discriminate against Plaintiff based on his disability – wasting syndrome/lipodystrophy, by denying him life-saving medication, Serostim, without which he can die.

52. This discrimination is based in part on the fact that, although Plaintiff's lipodystrophy is not caused by HIV or antiretroviral medications used to treat it, his disability is essentially the same as lipodystrophy caused by either HIV or the medications used to treat it. Essentially, Defendants are penalizing Plaintiff for his HIV-negative status.

## VII. JURY DEMAND

53. Plaintiff demands that this case be tried to a jury.

## **VIII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff requests this Court to:

1. Reverse and set aside the decision of the DHHS and award such benefits as to which Plaintiff is entitled;
  2. Award Plaintiff all out of pocket moneys spent through the end of this case,
  3. Award Plaintiff reasonable attorney's fees and costs; and
  4. Grant Plaintiff such additional and alternative relief as equity and justice may require.

Dated: 8/16/2018

## **PEOPLE WITH DISABILITIES FOUNDATION**

By: /s/ Zoya Yarnykh  
ZOYA YARNYKH  
Attorneys for Plaintiff